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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,465	02/07/2005	Matthew H T Bui	306J-000220US	4663

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,465	BUI ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/31/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (1-3 and 5-23, to the extent the CAIX is a polypeptide) in the reply filed on September 18, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-25 are pending.

Claims 4, 24 and 25, drawn to non-elected inventions are withdrawn from examination.

Claims 1-3 and 5-23 to the extent the CAIX is a polypeptide are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3 and 5-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on a method of aiding in a renal cell carcinoma (RCC) prognosis comprising quantifying expressed carbonic anhydrase IX (CAIX) in a sample from a subject diagnosed with RCC. The specification does not clearly define CAIX. It does note CAIX non-limiting examples of CAIX, such as a fragment of CAIX, or the like and cites terms synonymous with CAIX, see page 11, section 0029; and page 13, section 0036. This lack of definition suggests the CAIX molecule could possibly be a gene having a nucleotide sequence such as deletion, substitution or addition of a nucleotide has occurred in such the nucleotide sequence or molecule derived from a naturally occurring mutation due to a difference in organism species.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

The structure of naturally occurring allelic sequences are not defined. The skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless

of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, in *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B (1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

At the time the application was filed Applicants seem not to clearly define a CAIX molecule. The specification does not evidence the possession of all CAIX molecules. There is insufficient support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 6-14 and 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 14 read on method of aiding in a renal cell carcinoma prognosis comprising quantifying expressed carbonic anhydrase IX (CAIX) in a patient sample. However, the claims do not note how the CAIX is quantified. These claims are vague and indefinite because they recite incomplete method steps. The claims do not recite a *complete* method. Applicants must present the claim in clear, concise and definitive language for one of ordinary skill in the art to clearly distinguish what is being claimed. Applicants are requested to provide all the components required for the implementation of the claimed method. While it is clear that that there is quantification of CAIX, wherein it is a polypeptide in a sample it is not clear how this implemented. It is not clear what is the diagnostic tool used in the assay and the claim continues to be indefinite because it merely recites a use without all the required active and positive steps delimiting how the use is actually practiced.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 6-14 and 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005). Zisman discloses a method of quantifying expressed CAIX in samples from patients with RCC and the data and characteristics of this evaluated population were assessed using Stata statistical software, see page 1650, 2nd column, last paragraph of Survival...section and Results. The disclosed system allows one of ordinary skill in the art to prognosticate and determine survival differences imposed by different histologic types of RCC, see page 1657. While the patent does not explicitly list the percentages referenced in the claims, the disclosure reads on Applicants' active step listed in claim 1, quantifying expressed CAIX and hence reads on a method of aiding in RCC prognosis and correlating the expression data with a probability of RCC prognosis, wherein the quantified CAIX

expression data comprises the claimed quantification percentages and correlates with positive responses.

8. Claims 1-3, 5-11, 14-16 and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005). The patent discloses a method of quantitating MN antigen also art known as CAIX located in a patient sample implementing an immunoassay, such as immunohistochemical assays, ELISAS or fluorometric assays, see attached database sheet; column 5, lines 49-column 6, line 3; column 6, lines 47-54; column 36, line 44-column 39, line 35; and Example 13 starting in column 55. While the patent does not explicitly list the percentages referenced in the claims, the disclosure reads on Applicants' active step listed in claim 1, quantifying expressed CAIX and hence reads on a method of aiding in RCC prognosis and correlating the expression data with a probability of RCC prognosis, wherein the quantified CAIX expression data comprises the claimed quantification percentages and correlates with positive responses.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3 and 5-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005). The teachings of the patent have been presented above. The patent does not teach the quantified CAIX expression data in a computer-readable form, wherein there is a programmable computer with a database and an algorithm.

However, Zisman teaches a method of quantifying expressed CAIX in samples from patients with RCC and the data and characteristics of this evaluated population using Stata statistical software, see page 1650, 2nd column, last paragraph of Survival...section and Results. The disclosed system allows one of ordinary skill in the art to prognosticate and determine survival differences imposed by different histologic types of RCC, see page 1657. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the computer based program of Zisman. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both documents that CAIX is a diagnostic marker for tumorigenicity and is prognostic for

neoplastic/pre-neoplastic disease, as well as the system of Zisman stratifies and analyzes data for discriminating patient prognosis, see patent, column 1, lines 15-25; and column 2, lines 1-9; and the entire Zisman article.

11. Claims 1-3 and 5-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005), and further in view of U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005). The teachings of Zisman have been presented in the 102 rejections section of this Office Action. Zisman does not teach quantifying CAIX expression data using immunohistochemical staining.

However, the patent does teach a method of quantifying expressed CAIX in samples from patients with RCC via immunohistochemical assays, see attached database sheet; column 5, lines 49-column 6, line 3; column 6, lines 47-54; column 36, line 44-column 39, line 35; and Example 13 starting in column 55. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the immunohistochemical staining of the patent. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both documents that CAIX is a diagnostic marker for tumorigenicity and is prognostic for neoplastic/pre-neoplastic disease, as well immunohistochemical assays are well established procedures routinely used to detect polypeptides.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
10 December 2007

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER